

Outpatient prescription drugs means all prescription drugs covered by Medicare Part B.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6); and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).

Patient care services means any tasks performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters; or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and speech-language pathology services means those particular services identified by the CPT and HCPCS codes on the HCFA web site (and in annual updates published in the **Federal Register**). All services identified on the HCFA web site and in annual updates are physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of these regulations. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services

for purposes of these regulations includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment;

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services; or

(iv) Speech-language pathology services that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

(2) *Occupational therapy services*, meaning those services described at section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician, during the time the independent contractor is furnishing patient care services (as defined in this section) to the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract fits

in the personal services exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules at § 424.80(b)(3) of this chapter (see also section 3060.3 of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process). Referrals from an independent contractor who is a physician in the group are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these services that are covered by Medicare):

(1) *Orthotics*, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics*, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies*, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register**. All services identified on the HCFA web site and in annual updates are radiation therapy services and supplies for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a radiation therapy service or supply for purposes of these regulations. The list of codes for radiation therapy services and supplies identified on the HCFA web site and in annual updates is based on

section 1861(s)(4) of the Act and § 410.35 of this chapter but does not include nuclear medicine procedures.

Radiology and certain other imaging services means those particular services identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register** (except as otherwise specifically excluded on the HCFA web site and in annual updates). All services identified on the HCFA web site and in annual updates are *radiology and certain other imaging services* for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a *radiology or certain other imaging service* for purposes of these regulations. The list of *radiology and certain other imaging services* set forth on the HCFA web site and in annual updates includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, or other imaging services, computerized axial tomography, or magnetic resonance imaging, as covered under section 1861(s)(3) of the Act and §§ 410.32 and 410.34 of this chapter but does not include—

(1) X-ray, fluoroscopy, or ultrasonic procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology procedures that are integral to the performance of, and performed during, nonradiological medical procedures; and

(3) Nuclear medicine procedures.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not *personally* performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of

any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not *personally* performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy

with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior parking garages. For purposes of this rule, the "same building" does not include a mobile vehicle, van, or trailer.

5. Section 411.352 is added to read as follows:

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may not be organized or owned (in whole or in part) by another medical practice that is an operating physician practice (regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this rule, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a

single legal entity may itself own subsidiary entities.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined in this section.

(c) *Range of care.* Each physician who is a *member of the group*, as defined in § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, substantially all of the patient care services of the physicians who are *members of the group* (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. "Patient care services" must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this "substantially all test" and related supportive documentation must be made available to the Secretary upon request.

(3) The "substantially all test" does not apply to any group practice that is located solely in an HPSA, as defined in § 411.351.

(4) For a group practice located outside of an HPSA (as defined in § 411.351), any time spent by a group practice member providing services in an HPSA should not be used to calculate whether the group practice has met the "substantially all test," regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the "start up" period (not to exceed 12 months) that begins on the date of the initial formation of a new

group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this rule prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries).

(ii) Consolidated billing, accounting, and financial reporting.

(iii) Centralized utilization review.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services "incident to" those personally performed services as defined in § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

(2) "Overall profits" means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The share of overall profits will be deemed *not* to relate directly to the volume or value of referrals if *one* of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(iv) Overall profits are divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(3) A productivity bonus for personally performed services (including services "incident to" those personally performed services as defined in § 411.351) will be deemed *not* to relate directly to the volume or value of referrals of DHS if *one* of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). The methodology for establishing RVUs is set forth in § 414.22 of this chapter.

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(iv) The bonus is calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(4) Supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of

compensation, must be made available to the Secretary upon request.

6. Section 411.353 is revised to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff; however, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal laws, rules, and regulations.

7. Section 411.354 is added to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities (not including an agent of the physician, the immediate family member, or the entity furnishing DHS).

(3) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in a retirement plan;

(ii) Stock options and convertible securities until the stock options are exercised or the convertible securities are converted to equity (before this time they are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section); or

(iv) An “under arrangements” contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing

DHS “under arrangements” to the hospital.

(4) An ownership or investment interest that meets an exception set forth in §§ 411.355 or 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, interest payments on secured obligations, or the like.

(5) *Indirect ownership or investment interest.* (i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests between them; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) The entity furnishing DHS need not know, or act in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(c) *Compensation arrangement.* A compensation arrangement can be any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An “under arrangements” contract between a hospital and an entity providing DHS “under arrangements” to the hospital creates a compensation arrangement for purposes of these regulations.

(1) A compensation arrangement does not include any of the following:

(i) The portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term “remuneration” in § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(ii) Payments made by a consultant to a referring physician under § 414.65(e) of this chapter.

(2) *Indirect compensation arrangement.* An *indirect* compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of

persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a *direct* financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and these regulations in subpart J of this part.

(1) Compensation will be considered "set in advance" if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement between the parties in sufficient detail so that it can be objectively verified. The payment amount must be fair market value compensation for services or items

actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician at the time of the initial agreement or during the term of the agreement. Percentage compensation arrangements do not constitute compensation that is "set in advance" in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

(2) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

(3) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "other business generated between the parties" so long as the compensation is fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.

(4) A physician's compensation may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is fixed in advance for the term of the agreement;

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals);

(iii) Complies with an applicable exception under §§ 411.355 or 411.357; and

(iv) Complies with the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgement.

8. Section 411.355 is revised to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, "physician services" includes only those "incident to" services (as defined in § 411.351) that are physician services under § 410.20(a) of this chapter.

(3) All other "incident to" services (for example, diagnostic tests, physical therapy) are outside the scope of paragraph (a) of this section.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined in § 411.351), but not necessarily in the same space or part of the building, in which—

(A) The referring physician (or another physician who is a member of the same group practice) furnishes substantial physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal

health care payer, or a private payer, even though the unrelated services may lead to the ordering of DHS;

(B) The physician services that are unrelated to the furnishing of DHS in paragraph (b)(2)(i)(A) of this section must represent substantially the full range of physician services unrelated to the furnishing of DHS that the referring physician routinely provides (or, in the case of a referring physician who is a member of a group practice, the full range of physician services that the physician routinely provides for the group practice); and

(C) The receipt of DHS (whether payable by a Federal health care program or a private payer) is not the primary reason the patient comes in contact with the referring physician or his or her group practice.

(ii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They must be billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group" (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of § 424.80(b)(6) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood

glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards located in § 424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "furnished" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section, a private home does not include a nursing, long-term care, or other facility or institution.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its

contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M of this chapter, which set forth qualifying conditions for Medicare contracts; enrollment, entitlement, and disenrollment under Medicare contracts; Medicare contract requirements; and change of ownership and leasing of facilities: effect on Medicare contracts.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

(d) *Clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. ("Components" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation.);

(B) Is licensed to practice medicine in the State;

(C) Has a *bona fide* faculty appointment at the affiliated medical school; and

(D) Provides either substantial academic or substantial clinical

teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center.

(ii) The total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act.

(2) The "academic medical center" for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate);

(ii) An affiliated faculty practice plan that is a 501(c)(3) or (c)(4) of the Internal Revenue Code nonprofit, tax-exempt organization under IRS regulations (or is a part of such an organization under an umbrella designation); and

(iii) One or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members.

(f) *Implants in an ASC.* Implants, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME that meet the following conditions:

(1) The implant is furnished by the referring physician or a member of the referring physician's group practice in a Medicare-certified ASC (under part 416 of this chapter) with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure

performed in the same ASC where the implant is furnished.

(3) The arrangement for the furnishing of the implant does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the implants complies with all Federal and State laws and regulations.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to and implanted in the patient.

(g) *EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility.* EPO and other dialysis-related outpatient prescription drugs that are identified by the CPT and HCPCS codes on the HCFA web site, <http://www.hcfa.gov>, and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "furnished" means that the EPO or drugs are either administered or dispensed to a patient in or by the ESRD facility, even if the EPO or drugs are furnished to the patient at home. "Dialysis-related drugs" means certain drugs required for the efficacy of dialysis, as identified on the HCFA web site and in annual updates.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the EPO and other dialysis related drugs complies with all Federal and State laws and regulations.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.*

Preventive screening tests, immunizations, and vaccines that are covered by Medicare and identified by the CPT and HCPCS codes included on the HCFA web site and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to HCFA-mandated frequency limits.

(2) The preventive screening tests, immunizations, and vaccines are

reimbursed by Medicare based on a fee schedule.

(3) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all Federal and State laws and regulations.

(5) To qualify under this exception, the preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed on the HCFA web site and in annual updates.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the eyeglasses or contact lenses complies with all Federal and State laws and regulations.

9. In § 411.357, paragraph (j) is added and reserved, and paragraphs (k), (l), (m), (n), (o), and (p) are added to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(j) [Reserved]

(k) *Non-monetary compensation up to \$300.* Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per year, if all of the following conditions are satisfied:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(3) The compensation arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(l) *Fair market value compensation.* Compensation resulting from an

arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) It is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) It specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) It specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician.

(4) It involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, has been approved by the OIG under a favorable advisory opinion issued in accordance with part 1008 of this title, or does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties.

(2) The compensation is offered only during periods when the medical staff members are making rounds or

performing other duties that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is consistent with the types of benefits offered to medical staff members—

(i) By other hospitals within the same local region; or

(ii) If no such hospitals exist within the same local region, by comparable hospitals in comparable regions.

(6) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

(7) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(8) The compensation arrangement does not violate the Federal anti-kickback provisions in section 1128B(b) of the Act.

(n) *Risk sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings ascribed to those terms in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in the hospital's local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), "compliance training" means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding,

reasonable and necessary services, documentation, unlawful referral arrangements).

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

B. Part 424 is amended as follows:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Certification and Plan of Treatment Requirements

2. In § 424.22, paragraph (d) is revised to read as set forth below, and paragraphs (e), (f), and (g) are removed.

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/ investment and compensation; exceptions to the referral prohibition

related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; Program No. 93.774, Medicare-Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: October 6, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

Dated: October 16, 2000.

Donna E. Shalala,

Secretary.

Note: The following attachment will not appear in the Code of Federal Regulations.

Attachment

List of CPT ¹/HCPCS Codes Used To Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)

Clinical Laboratory Services

Include CPT codes for all clinical laboratory services in the 80000 series, except *Exclude* CPT codes for the following blood component collection services:

86890 Autologous blood process
86891 Autologous blood, op salvage
86915 Bone marrow/stem cell prep
86927 Plasma, fresh frozen
86930 Frozen blood prep
86931 Frozen blood thaw
86932 Frozen blood freeze/thaw
86945 Blood product/irradiation
86950 Leukocyte transfusion
86965 Pooling blood platelets
86985 Split blood or products

Include HCPCS level 2 codes for other clinical laboratory services:

G0001 Drawing blood for specimen
G0026 Fecal leukocyte examination
G0027 Semen analysis
G0103 Psa, total screening
G0107 CA screen; fecal blood test
G0123 Screen cerv/vag thin layer
G0124 Screen c/v thin layer by MD
G0141 Scr c/v cyto, autosys and md
G0143–G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
P2028 Cephalin flocculation test
P2029 Congo red blood test
P2031 Hair analysis
P2033 Blood thymol turbidity
P2038 Blood mucoprotein

P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys
P7001 Culture bacterial urine
P9612 Catheterize for urine spec
P9615 Urine specimen collect mult
Q0111 Wet mounts/w preparations
Q0112 Potassium hydroxide preps
Q0113 Pinworm examinations
Q0114 Fern test
Q0115 Post-coital mucous exam

Physical Therapy/Occupational Therapy/Speech-Language Pathology

Include the following CPT codes for the physical therapy/occupational therapy/speech-language pathology services in the 97000 series:

97001 Pt evaluation
97002 Pt re-evaluation
97003 Ot evaluation
97004 Ot re-evaluation
97010 Hot or cold packs therapy
97012 Mechanical traction therapy
97014 Electric stimulation therapy
97016 Vasopneumatic device therapy
97018 Paraffin bath therapy
97020 Microwave therapy
97022 Whirlpool therapy
97024 Diathermy treatment
97026 Infrared therapy
97028 Ultraviolet therapy
97032 Electrical stimulation
97033 Electric current therapy
97034 Contrast bath therapy
97035 Ultrasound therapy
97036 Hydrotherapy
97039 Physical therapy treatment
97110 Therapeutic exercises
97112 Neuromuscular reeducation
97113 Aquatic therapy/exercises
97116 Gait training therapy
97124 Massage therapy
97139 Physical medicine procedure
97140 Manual therapy
97150 Group therapeutic procedures
97504 Orthotic training
97520 Prosthetic training
97530 Therapeutic activities
97532 Cognitive skills development
97533 Sensory integration
97535 Self care mngmt training
97537 Community/work reintegration
97542 Wheelchair mngmt training
97545 Work hardening
97546 Work hardening add-on
97703 Prosthetic checkout
97750 Physical performance test
97799 Physical medicine procedure

Include CPT codes for physical therapy/occupational therapy/speech-language pathology services *not* in the 97000 series:

64550 Apply neurostimulator
90901 Biofeedback train, any meth
90911 Biofeedback peri/uro/rectal
92506 Speech/hearing evaluation
92507–92508 Speech/hearing therapy
92510 Rehab for ear implant

92526 Oral function therapy
93797 Cardiac rehab
93798 Cardiac rehab/monitor
94667–94668 Chest wall manipulation
94762 Measure blood oxygen level
95831 Limb muscle testing, manual
95832 Hand muscle testing, manual
95833–95834 Body muscle testing, manual
95851–95852 Range of motion measurements
96105 Assessment of aphasia
96110 Developmental test, lim
96111 Developmental test, extend
96115 Neurobehavior status exam

Include HCPCS level 2 codes for the following physical therapy/occupational therapy/speech-language pathology services:

G0193 Endoscopic study swallow functn
G0194 Sensory testing endoscopic stud
G0195 Clinical eval swallowing functn
G0196 Eval of swallowing with radioopa
G0197 Eval of pt for prescip speech devi
G0198 Patient adaption & train for spe
G0199 Reevaluation of patient use spec
G0200 Eval of patient prescip of voice p
G0201 Modi for training in use voice pro
Q0086 Physical therapy evaluation/

Radiology

Include the following radiology and certain other imaging services in the CPT 70000 series:

70100–70110 X-ray exam of jaw
70120–70130 X-ray exam of mastoids
70134 X-ray exam of middle ear
70140–70150 X-ray exam of facial bones
70160 X-ray exam of nasal bones
70190–70200 X-ray exam of eye sockets
70210–70220 X-ray exam of sinuses
70240 X-ray exam, pituitary saddle
70250–70260 X-ray exam of skull
70300–70310 X-ray exam of teeth
70320 Full mouth x-ray of teeth
70328 X-ray exam of jaw joint
70330 X-ray exam of jaw joints
70336 Magnetic image, jaw joint
70350 X-ray head for orthodontia
70355 Panoramic x-ray of jaws
70360 X-ray exam of neck
70370 Throat x-ray & fluoroscopy
70371 Speech evaluation, complex
70380 X-ray exam of salivary gland
70450 CT head/brain w/o dye
70460 CT head/brain w/dye
70470 CT head/brain w/o&w dye
70480 CT orbit/ear/fossa w/o dye
70481 CT orbit/ear/fossa w/dye
70482 CT orbit/ear/fossa w/o&w dye

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70486	CT maxillofacial w/o dye	72170-72190	X-ray exam of pelvis	74230	Cinema x-ray, throat/esoph
70487	CT maxillofacial w/dye	72191	CT angiograph pelv w/o&w dye	74240-74245	X-ray exam, upper gi tract
70488	CT maxillofacial w/o&w dye	72192	CT pelvis w/o dye	74246-74249	Contrst x-ray uppr gi tract
70490	CT soft tissue neck w/o dye	72193	CT pelvis w/dye	74250	X-ray exam of small bowel
70491	CT soft tissue neck w/dye	72194	CT pelvis w/o&w dye	74290	Contrast x-ray, gallbladder
70492	CT sft tsue nck w/o & w/dye	72195	MRI pelvis w/o dye	74291	Contrast x-rays, gallbladder
70496	CT angiography, head	72196	MRI pelvis w/dye	74710	X-ray measurement of pelvis
70498	CT angiography, neck	72197	MRI pelvis w/o&w dye	75552	Heart MRI for morph w/o dye
70540	MRI orbit/face/neck w/o dye	72200-72202	X-ray exam sacroiliac joints	75553	Heart MRI for morph w/dye
70542	MRI orbit/face/neck w/dye	72220	X-ray exam of tailbone	75554	Cardiac MRI/function
70543	MRI orbt/fac/nck w/o&w dye	73000	X-ray exam of collar bone	75555	Cardiac MRI/limited study
70544	MR angiography head w/o dye	73010	X-ray exam of shoulder blade	75635	CT angio abdominal arteries
70545	MR angiography head w/dye	73020-73030	X-ray exam of shoulder	76000	Fluoroscope examination
70546	MR angiograph head w/o&w dye	73050	X-ray exam of shoulders	76006	X-ray stress view
70547	MR angiography neck w/o dye	73060	X-ray exam of humerus	76010	X-ray, nose to rectum
70548	MR angiography neck w/dye	73070-73080	X-ray exam of elbow	76020	X-rays for bone age
70549	MR angiograph neck w/o&w dye	73090	X-ray exam of forearm	76040	X-rays, bone evaluation
70551	MRI brain w/o dye	73092	X-ray exam of arm, infant	76061-76062	X-rays, bone survey
70552	MRI brain w/dye	73100-73110	X-ray exam of wrist	76065	X-rays, bone evaluation
70553	MRI brain w/o&w dye	73120-73130	X-ray exam of hand	76066	Joint(s) survey, single film
71010-71022	Chest x-ray	73140	X-ray exam of finger(s)	76090	Mammogram, one breast
71023	Chest x-ray and fluoroscopy	73200	CT upper extremity w/o dye	76091	Mammogram, both breasts
71030	Chest x-ray	73201	CT upper extremity w/dye	76092	Mammogram, screening
71034	Chest x-ray and fluoroscopy	73202	CT uppr extremity w/o&w dye	76093	Magnetic image, breast
71035	Chest x-ray	73206	CT angio upr extrm w/o&w dye	76094	Magnetic image, both breasts
71100	X-ray exam of ribs	73218	MRI upper extremity w/o dye	76100	X-ray exam of body section
71101	X-ray exam of ribs/chest	73219	MRI upper extremity w/dye	76101	Complex body section x-ray
71110	X-ray exam of ribs	73220	MRI uppr extremity w/o&w dye	76102	Complex body section x-rays
71111	X-ray exam of ribs/chest	73221	MRI joint upr extrem w/o dye	76120	Cinematic x-rays
71120-71130	X-ray exam of breastbone	73222	MRI joint upr extrem w/ dye	76125	Cinematic x-rays add-on
71250	CT thorax w/o dye	73223	MRI joint upr extr w/o&w dye	76150	X-ray exam, dry process
71260	CT thorax w/dye	73500-73510	X-ray exam of hip	76370	CAT scan for therapy guide
71270	CT thorax w/o&w dye	73520	X-ray exam of hips	76375	3d/holograph reconstr add-on
71275	CT angiography, chest	73540	X-ray exam of pelvis & hips	76380	CAT scan follow-up study
71550	MRI chest w/o dye	73550	X-ray exam of thigh	76390	Mr spectroscopy
71551	MRI chest w/dye	73560	X-ray exam of knee, 1 or 2	76400	Magnetic image, bone marrow
71552	MRI chest w/o&w dye	73562	X-ray exam of knee, 3	76499	Radiographic procedure
71555	MRI angio chest w or w/o dye	73564	X-ray exam, knee, 4 or more	76506	Echo exam of head
72010-72020	X-ray exam of spine	73565	X-ray exam of knees	76511-76512	Echo exam of eye
72040-72052	X-ray exam of neck spine	73590	X-ray exam of lower leg	76513	Echo exam of eye, water bath
72069	X-ray exam of trunk spine	73592	X-ray exam of leg, infant	76516-76519	Echo exam of eye
72070-72074	X-ray exam of thoracic spine	73600-73610	X-ray exam of ankle	76536	Echo exam of head and neck
72080-72090	X-ray exam of trunk spine	73620-73630	X-ray exam of foot	76604	Echo exam of chest
72100-72120	X-ray exam of lower spine	73650	X-ray exam of heel	76645	Echo exam of breast(s)
72125	CT neck spine w/o dye	73660	X-ray exam of toe(s)	76700-76705	Echo exam of abdomen
72126	CT neck spine w/dye	73700	CT lower extremity w/o dye	76770-76775	Echo exam abdomen back wall
72127	CT neck spine w/o&w dye	73701	CT lower extremity w/dye	76778	Echo exam kidney transplant
72128	CT chest spine w/o dye	73702	CT lwr extremity w/o&w dye	76800	Echo exam spinal canal
72129	CT chest spine w/dye	73706	CT angio lwr extr w/o&w dye	76805-76815	Echo exam of pregnant uterus
72130	CT chest spine w/o&w dye	73718	MRI lower extremity w/o dye	76816	Echo exam follow-up/repeat
72131	CT lumbar spine w/o dye	73719	MRI lower extremity w/dye	76818	Fetl biophys profil w/stress
72132	CT lumbar spine w/dye	73720	MRI lwr extremity w/o&w dye	76819	Fetl biophys profil w/o str
72133	CT lumbar spine w/o&w dye	73721	MRI joint of lwr extre w/o d	76825-76828	Echo exam of fetal heart
72141	MRI neck spine w/o dye	73722	MRI joint of lwr extr w/dye	76830	Echo exam, transvaginal
72142	MRI neck spine w/dye	73723	MRI joint lwr extr w/o&w dye	76831	Echo exam, uterus
72146	MRI chest spine w/o dye	73725	MR ang lwr ext w or w/o dye	76856-76857	Echo exam of pelvis
72147	MRI chest spine w/dye	74000-74020	X-ray exam of abdomen	76870	Echo exam of scrotum
72148	MRI lumbar spine w/o dye	74022	X-ray exam series, abdomen	76872	Echo exam, transrectal
72149	MRI lumbar spine w/dye	74150	CT abdomen w/o dye	76873	Echograp trans r, pros study
72156	MRI neck spine w/o&w dye	74160	CT abdomen w/dye	76880	Echo exam of extremity
72157	MRI chest spine w/o&w dye	74170	CT abdomen w/o&w dye	76885-76886	Echo exam, infant hips
72158	MRI lumbar spine w/o&w dye	74175	CT angio abdom w/o&w dye	76970	Ultrasound exam follow-up
		74181	MRI abdomen w/o dye	76977	Us bone density measure
		74182	MRI abdomen w/dye	76999	Echo examination procedure
		74183	MRI abdomen w/o&w dye		Include the following CPT codes for echocardiography and vascular ultrasound:
		74185	MRI angio, abdom w or w/o dy		
		74210	Contrst x-ray exam of throat		
		74220	Contrast x-ray, esophagus		

93303-93304 Echo transthoracic
 93307-93308 Echo exam of heart
 93320-93321 Doppler echo exam, heart, if used in conjunction with 93303-93308
 93325 Doppler color flow add-on, if used in conjunction with 93303-93308
 93875-93882 Extracranial study
 93886-93888 Intracranial study
 93922-93924 Extremity study
 93925-93926 Lower extremity study
 93930-93931 Upper extremity study
 93965-93971 Extremity study
 93975-93979 Vascular study
 93980-93981 Penile vascular study
 93990 Doppler flow testing

Include miscellaneous other HCPCS level 2 codes for radiology and certain other imaging services:

G0050 Residual urine by ultrasound
 G0131-132 CT scan, bone density study
 G0188 Xray lwr extrmty-full lngth
 R0070 Transport portable x-ray
 R0075 Transport port x-ray multipl

Radiation Therapy Services and Supplies

Include CPT codes for all radiation therapy services and supplies in the CPT 70000 series:

77261-77263 Radiation therapy planning
 77280-77295 Set radiation therapy field
 77299 Radiation therapy planning
 77300-77315 Radiation therapy dose plan
 77321 Radiation therapy port plan
 77326-77328 Radiation therapy dose plan
 77331 Special radiation dosimetry
 77332-77334 Radiation treatment aid(s)
 77336-77370 Radiation physics consult
 77399 External radiation dosimetry
 77401-77416 Radiation treatment delivery

77417 Radiology port film(s)
 77427 Radiation tx management, x5
 77431 Radiation therapy management
 77432 Stereotactic radiation trmt
 77470 Special radiation treatment
 77499 Radiation therapy management
 77520 Proton trmt, simple w/o comp
 77522 Proton trmt, simple w/comp
 77523 Proton trmt, intermediate
 77525 Proton treatment, complex
 77600-77620 Hyperthermia treatment
 77750 Infuse radioactive materials
 77761 Apply intrcav radiat simple
 77762 Apply intrcav radiat interm
 77763 Apply intrcav radiat compl
 77776 Apply interstit radiat simpl
 77777 Apply interstit radiat inter
 77778 Apply iterstit radiat compl
 77781-77784 High intensity brachytherapy
 77789 Apply surface radiation
 77790 Radiation handling
 77799 Radium/radioisotope therapy

Include CPT codes for radiation therapy classified elsewhere:

31643 Diag bronchoscope/catheter
 50559 Renal endoscopy/radiotracer
 55859 Percut/needle insert, pros
 61770 Incise skull for treatment
 61793 Focus radiation beam

Preventive Screening Tests, Immunizations and Vaccines

The following CPT and HCPCS codes are excluded under § 411.355(h) as screening tests:

76092 Mammogram, screening
 76977 Us bone density measure
 G0103 Psa, total screening
 G0107 CA screen; fecal blood test
 G0123 Screen cerv/vag thin layer
 G0124 Screen c/v thin layer by MD
 G0141 Scr c/v cyto,autosys and md
 G0143-G0145 Scr c/v cyto, thin layer, rescr
 G0147 Scr c/v cyto, automated sys
 G0148 Scr c/v cyto, autosys, rescr
 P3000 Screen pap by tech w md supv
 P3001 Screening pap smear by phys

The following CPT codes are excluded under § 411.355(h) as vaccines:

90657 Flu vaccine, 6-35 mo, im
 90658 Flu vaccine, 3 yrs, im
 90659 Flu vaccine, whole, im
 90732 Pneumococcal vacc, adult/ill
 90744 Hepb vacc ped/adol 3 dose im
 90746 Hep b vaccine, adult, im
 90747 Hepb vacc, ill pat 4 dose im
 90748 Hep b/hib vaccine, im

Drugs Used by Patients Undergoing Dialysis

The following HCPCS codes are excluded under § 411.355(g) as EPO and other dialysis related outpatient prescription drugs furnished in or by an ESRD facility:

J0635 Calcitriol injection
 J0895 Deferoxamine meslyate inj
 J1750 Iron dextran
 J2915 NA Ferric Gluconate Complex
 J2997 Alteplase recombinant
 Q9920 Epoetin with hct ≤ 20
 Q9921 Epoetin with hct = 21
 Q9922 Epoetin with hct = 22
 Q9923 Epoetin with hct = 23
 Q9924 Epoetin with hct = 24
 Q9925 Epoetin with hct = 25
 Q9926 Epoetin with hct = 26
 Q9927 Epoetin with hct = 27
 Q9928 Epoetin with hct = 28
 Q9929 Epoetin with hct = 29
 Q9930 Epoetin with hct = 30
 Q9931 Epoetin with hct = 31
 Q9932 Epoetin with hct = 32
 Q9933 Epoetin with hct = 33
 Q9934 Epoetin with hct = 34
 Q9935 Epoetin with hct = 35
 Q9936 Epoetin with hct = 36
 Q9937 Epoetin with hct = 37
 Q9938 Epoetin with hct = 38
 Q9939 Epoetin with hct = 39
 Q9940 Epoetin with hct ≥ 40

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